DMB

Display Date 9-11-00
Publication Date 9-12-00
Certifier SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1311]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Export of Medical Devices—Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

N 2

Export of Medical Devices—Foreign Letters of Approval—Federal Food, Drug, and Cosmetic Act—21 U.S.C. 381(e)(2) (OMB Control No. 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. FDA uses the written authorization from the foreign country to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

In the **Federal Register** of June 20, 2000 (65 FR 38288), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Statute	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act	20	1	20	2.5	50
Total					50

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the experience of FDA's medical device program personnel, who estimate that completion of the requirements of this collection of information should take approximately 2.5 hours to complete. Prior to the enactment of the Food and Drug Export Reform and Enhancement Act of 1996, FDA received approximately 800 requests from U.S. firms to export

medical devices under section 801(e)(2) of the act. The enactment of the Food and Drug Export Reform and Enhancement Act of 1996 has greatly reduced the number of export permit requests made to the present estimated 20 per year.

Dated: September 5, 2000

William Hubbard

William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F